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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/476,567	06/07/95	WILSON R	CARPR-0022C3

18N2/0806
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GUZO, D EXAMINER	
ART UNIT	PAPER NUMBER
1805	4

DATE MAILED: 08/06/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.	Applicant(s)
08/476,567	Wilson et al.
Examiner	**Group Art Unit**
David Guzo	1805

☒ Responsive to communication(s) filed on *Jun 7, 1995* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *Three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-38* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-38* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 23, 24 and 35 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 53-54 and 56 of copending application Serial No. 08/302,241. This is a *provisional* double patenting rejection since the conflicting claims have not in fact been patented.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 14-22, 25-28, 36-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 51-63 of copending application Serial No. 08/302,241. Although the conflicting claims are not identical, they are not patentably distinct from each other because the recombinant DNAs containing the complete sequence of a GS gene, vectors containing said GS gene and methods for co-amplifying genes of interest recited in S.N.

08/302,241 (the '241 application) differ only slightly in scope from those recited in the instant application or differ in the physical description of the subject matter (i.e. applicants recite, in Claim 61 of the '241 application, "An amplifiable recombinant DNA..." which encodes the complete sequences of a GS gene, while in the instant application, applicants recite "A recombinant DNA which encodes the complete amino acid sequence of a glutamine synthetase (GS) gene."). Since the GS gene is amplifiable, it must be considered that the two sets of claims are not patentably distinct.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-34 and 36-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 5,122,464 (the '464 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed recombinant DNAs encoding GS genes, expression vectors containing said genes, methods for co-amplifying a non-GS gene of interest, use of the GS gene as a dominant selectable marker, etc. differ only in scope and encompass overlapping subject matter. For example, applicants in the '464 patent, recite co-amplification methods using recombinant vectors encoding any GS gene (said GS genes are now being claimed), applicants recite, in the '464 patent, "A plasmid including the GS minigene from plasmid pSVLGS.1." and now claim, in the instant application, the pSVLGS.1 plasmid, etc.

1. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention and/or failing to provide a written description of the invention.

2. Claims 8, 12 and 13 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Applicants claim a recombinant DNA from any species which hybridizes under high stringency conditions to a DNA encoding a GS protein. However, applicants have not presented any teachings on how this DNA is to be obtained. For example, applicants have not disclosed, in the instant specification, what is meant by "high stringency" hybridization conditions. Applicants have not disclosed how the skilled artisan would use a DNA which simply hybridizes to a GS gene since the DNA is not identified by function, i.e. the DNA identified can encode any protein or the DNA identified can be a non-coding sequence, etc.

Applicants claim the use of a GS gene as a hybridization probe but do not recite the conditions under which the probe is prepared, the conditions under which the DNA is used as a probe, the target to be identified by the probe, etc. Applicants also claim use of the GS gene in medical or diagnostic methods for detecting disease conditions; however, applicants present no teachings on how the skilled artisan would prepare and use the GS gene as a diagnostic probe for detection of any disease condition, applicants present no teachings on how the skilled artisan would use the GS gene in any medical or diagnostic procedure, etc. Applicants also do not cite any relevant portions of prior art documents to provide guidance for the skilled artisan to practice the claimed invention. Therefore, it

must be assumed that applicants have not provided a disclosure sufficient to enable the skilled artisan to practice the claimed invention without having to practice undue and excessive experimentation, with no guidance from applicants or the cited prior art. This type of trial and error experimentation is the antithesis of enablement under 35 USC 112, 1st paragraph.

Claims 8, 12-13, 15, 17-19, 26-38 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12-13 provide for the use of the GS gene, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicants are intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 12-13 are rejected under 35 USC 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 USC 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 13, which is recited as a product claim, is also vague in that it is a substantial duplicate of the product claimed in

Claim 1, without the use limitations. Since the intended use of a product carries no patentable weight, use limitations associated with a product are not considered in determining whether claims are substantial duplicates.

Claim 8 is vague in that the metes and bounds of the claimed DNAs are unclear because the hybridization conditions recited are not disclosed in the specification and because it is unclear what the DNA sequences identified by hybridization encode.

Claims 15 and 17 (and dependent claims 18-19, 26-38) are vague in the recitation of the phrase "capable...of expressing..." The capacity of a compound or composition to perform some function is merely a latent characteristic of said compound or composition and said language carries no patentable weight. Redrafting Claim 15, for example, to read on: --The vector of Claim 14, wherein said vector is an expression vector which expresses the recombinant DNA sequence of claim 1 in a host cell transformed with said expression vector.--

Claims 34-35 recite an intended use of the claimed vector. It is noted that the intended use of a compound or composition carries no patentable weight and is not proper claim language.

No Claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1805 by facsimile transmission. Papers should be faxed to Art Unit 1805 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (Nov. 16, 1993) and 1157 OG 94 (Dec. 28, 1993) (See 37 CFR 1.6(d)). The Art Unit 1805 fax number is (703) 308-0294. NOTE: If applicants do submit a paper by fax, the original signed copy should be retained by applicants or applicants' representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The Examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mindy Fleisher, can be reached on (703) 308-0407. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

David Guzo
July 30, 1996

DAVID GUZO
PRIMARY EXAMINER
GROUP 1800